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सिगरेट — नमूनें

(दूसरा पुनरीक्षण)

Indian Standard

CIGARETTES — SAMPLING

(Second Revision)

ICS 65.160

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

July 2008

Price Group 6

Tobacco and Tobacco Products Sectional Committee, FAD 4

NATIONAL FOREWORD

This Indian Standard (Second Revision) which is identical with ISO 8243 : 2006 'Cigarettes — Sampling' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Tobacco and Tobacco Products Sectional Committee and approval of the Food and Agriculture Division Council.

This standard was first published in 1991 and subsequently revised in 1996 to align it with ISO 8243 : 1991. The second revision of this standard is being brought about to align it with the latest edition of ISO 8243 : 2006 under dual numbering.

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
b) Comma(,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 2602 : 1980 Statistical interpretation of test results — Estimation of the mean — Confidence interval	IS 14277 : 1996 Statistical interpretation of test results — Estimation of mean, standard deviation and regression coefficient — Confidence interval	Technically Equivalent
ISO 5725-2 : 1994 Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of	IS 15393 (Part 2) : 2003 Accuracy (trueness and precision) of measurement methods and results : Part 2 Basic method for the determination of repeatability and reproducibility of a standard measurement method	Identical

The technical committee responsible for the preparation of this standard has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 4387 : 2000	Cigarettes — Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine
ISO 8454 : 1995	Cigarettes — Determination of carbon monoxide in the vapour phase of cigarette smoke — NDIR method
ISO 10315 : 2000	Cigarettes — Determination of nicotine in smoke condensates — Gas-chromatographic method
ISO 10362-1 : 1999	Cigarettes — Determination of water in smoke condensates — Part 1: Gas-chromatographic method

In reporting the result of a test or analysis made in accordance with this standard, if the final value, observed or calculated, is to be rounded off, it shall be done in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'.

Indian Standard
CIGARETTES — SAMPLING
(Second Revision)

1 Scope

This International Standard specifies two methods of providing representative samples of a population of cigarettes manufactured for sale. Different procedures are specified (see Table 1) according to whether sampling is undertaken at the point of sale or at a factory.

a) Sampling "at one point in time" provides for appraisal of the chosen properties of the cigarettes on that occasion. Sampling is carried out within as short a period as possible.

b) Sampling "over a period of time" provides for on-going appraisals. It can be considered for practical purposes as a series of samples each taken "at one point in time".

Table 1 — Sampling possibilities

Sampling procedures		Sampling mode	
		At one time (instantaneous)	**Over a period** (continuous)
A	At point of sale	Subclause 4.1	[a]
B	At a factory	Subclause 4.2	Clause 5

[a] Procedure A over a period of time is possible but is not specified in this International Standard.

This International Standard provides information on the statistical basis for the treatment of data and gives estimates, based on practical experience, of the typical confidence intervals for NFDPM, nicotine and CO yields which may be found when a product is sampled in accordance with this International Standard and smoked in accordance with the procedures specified in ISO 3308, ISO 3402, ISO 4387, ISO 8454, ISO 10315, ISO 10362-1 and ISO 10362-2.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2602:1980, *Statistical interpretation of test results — Estimation of the mean — Confidence interval*

ISO 4387:2000, *Cigarettes — Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine*

ISO 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

ISO 8454:1995, *Cigarettes — Determination of carbon monoxide in the vapour phase of cigarette smoke — NDIR method*

ISO 10315:2000, *Cigarettes — Determination of nicotine in smoke condensates — Gas-chromatographic method*

ISO 10362-1:1999, *Cigarettes — Determination of water in smoke condensates — Part 1: Gas-chromatographic method*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
factory
place of manufacture or its associated distribution depots or the warehouse of an importer

3.2
sale unit
quantity of cigarettes ready to be offered for sale to the public

NOTE The commonly sold packet of 20 cigarettes is used as the basis of this International Standard, but cigarettes are also sold loose and in other size packets.

3.3
carton
commercial package available within a factory

EXAMPLE Packets of 20 cigarettes are usually put into cartons of 200 cigarettes.

3.4
place of purchase
town, village or district within the area to be sampled, or that part of the area where the cigarettes are available

NOTE Examples of boundaries are those of cantons, local government districts, electoral areas, postal code areas or any boundaries in accordance with the geographical context, or others.

3.5
sampling point
specific location representing different kinds of sampling points (e.g. shop, specialist tobacco shop, auto-vending machine, supermarket, place in warehouse, place in factory) from which an increment is to be taken

3.6
population
aggregate of sale units to be sampled

NOTE The definition includes different sub-populations, three of which are given in 3.6.1 to 3.6.4.

3.6.1
population available to consumers
aggregate of sale units in retail outlets in a given area, at any time in a given time period

3.6.2
population manufactured for sale
aggregate of sale units at a factory

3.6.3
stratification
the division of a population into mutually exclusive and exhaustive sub-populations (called strata), which are thought to be more homogeneous, with respect to the characteristics investigated, than the total population

3.6.4
stratified sampling
in a population that can be divided into different mutually exclusive and exhaustive sub-populations (called strata), sampling carried out in such a way that specified proportions of the sample are drawn from the different strata and each stratum is sampled with at least one sampling unit

3.7
increment
sample of cigarettes taken at one time, at one sampling point

3.8
sub-increment
individual groups of cigarettes making up an increment

3.9
sub-period sample
increment taken when sampling over a period of time

3.10
laboratory sample
sample intended for laboratory inspection or testing

3.11
test sample
cigarettes for test taken at random from the laboratory sample and which are representative of each of the increments making up the laboratory sample

3.12
test portion
group of cigarettes randomly selected from the test sample for a determination

3.13
lot
definite quantity of some product, material or service, collected together and submitted for examination

NOTE An inspection lot may consist of several batches or parts of batches.

[ISO 3534-2:1993, definition 1.3.5]

4 Sampling mode: at one time

4.1 Procedure for sampling at the point of sale

4.1.1 Selection of the number and choice of sampling points

The number of sales units to be taken and the number of places of purchase to be randomly sampled is determined by the size of the area in which the cigarettes are sold. Select the appropriate numbers according to Table 2.

Table 2 — Sampling requirements

Total number of sampling points	Number of sampling points to be randomly sampled	Number of sales units to be taken at each sampling point for each laboratory sample
> 20	20	2
> 10 ⩽ 20	10	4
⩾ 5 ⩽10	5	8
4	4	10
3	3	14
2	2	20
1	1	40

If the procedure in Table 1 cannot be used, an alternative may be used with a justification in the sampling report. This may be independent of the size of the sales area, and not at random, but is satisfactory provided that a representative sample is taken. When used, a total of at least 40 sales units, when possible, shall be obtained.

NOTE Table 2 is applicable to a sample of 800 cigarettes. If there is more than one testing laboratory then the number of sales units is increased appropriately. It is necessary to make sure that each laboratory sample is representative of the population, e.g. if more than one carton is sampled they should be subdivided between the laboratory samples.

When a sales unit does not consist of a packet of 20 cigarettes, adjust the number of sales units sampled to produce the required number of cigarettes. In case of more laboratories special attention shall be given to the fact that each laboratory has a matched sample.

The sampling points from which the sales unit shall be obtained are to be distributed throughout the place of purchase.

The choice of sampling points shall, whenever possible, reflect the pattern of retail distribution of cigarettes in that sampling place to be sampled. This is usually done by defining several kinds of sampling points for each sampling scheme.

Each kind of sampling point is randomly sampled throughout the place of purchase and, in total, the increment shall make up a defined proportion of the whole sample.

Sampling shall only be carried out at another kind of sampling point after two unsuccessful attempts have been made at the specified points.

4.1.2 Constitution of the laboratory sample

4.1.2.1 From each sales unit take cigarettes in equal proportions for the laboratory samples (see Table 2).

4.1.2.2 If cigarettes of the same name and characteristics are required for several individual determinations, sufficient sale units shall be obtained from each sampling point. If several laboratories are to run tests, an equal number of sale units from each sampling point shall be contained in each laboratory sample.

4.1.2.3 Each laboratory sample shall be so labelled as to link it with all the manufacturing or packaging information that is relevant to the use of the data produced from tests upon it, such as:

a) name of the cigarettes and any other characteristics;

b) date of sampling;

c) place of purchase;

d) kind of sampling point (if defined);

e) sampling point (address of retail outlet);

f) destination (i.e. the laboratory to which the samples are destined);

g) marks on tax stamp, banderole (if any);

h) printed smoke yields (if any).

4.1.2.4 The sample(s) shall be obtained in as short a time as possible not exceeding 14 d.

4.1.2.5 All the samples shall be packed securely with adequate protection against damage (e.g. mechanical damage, severe changes in humidity, temperature) and sent to each laboratory by the most expeditious means.

4.1.2.6 A list of samples in each despatch on that day shall be sent to each laboratory, under separate cover in a separate mailing.

4.1.3 Constitution of the test sample

4.1.3.1 There will be several determinations (e.g. in ISO 4387 replicate smoking runs and smoking channels) carried out at each laboratory and the test sample will be divided into test portions, one for each determination.

4.1.3.2 The sub-increments in the laboratory sample are first individually identified. They are then inspected and, if several versions are found (e.g. cigarettes or packets with visible differences), they are separated so that separate tests can be carried out on each of them.

4.1.3.3 From the laboratory sample cigarettes are taken at random from each sub-increment making up the laboratory sample in such a way as to ensure that the cigarettes are representative of each of the sub-increments.

4.1.3.4 An equal number of cigarettes from each sub-increment is taken to provide a test portion on which one determination will be carried out.

4.1.3.5 Each test portion is labelled to show which sub-increments are represented.

NOTE This information may be needed later for the statistical analysis. If the variability of the sample is required, see Clause 6.

4.1.3.6 Each laboratory shall arrange its work as described in 4.1.3.1 to 4.1.3.5.

4.2 Procedure for sampling at the factory

4.2.1 Principles

4.2.1.1 Sampling is carried out by a suitably trained person. If the manufacturer so requests, the sampler will take a replicate sample for the manufacturer's use (see 4.1.2.1).

4.2.1.2 Samples shall only be taken from the finished product within a given short-time period (days) and should be ready for commercial distribution. All factories, stock rooms and warehouses containing finished products shall be included in the population to be sampled.

4.2.1.3 An external sampler shall bring written details of the purpose of test, name of the cigarette and number of sale units. Three copies shall be provided; one for the sampler's record, a second to be packed with the samples and a third for the manufacturer to act as a receipt for the goods taken. Factory internal sampling shall be well documented and contain the name of the cigarette, the name of the sampler, sampling locations and date of sampling.

4.2.2 Sampling

4.2.2.1 To make up each increment required, draw one or more cartons or packets of cigarettes at random from each sampling point to form the necessary laboratory samples.

4.2.2.2 Take the increments from as many sampling points as possible distributed between the factories where the cigarettes are made or imported and distributed as far as possible in proportion to the production at these factories, provided that every factory is sampled so as to ensure a statistically satisfactory representation of the population. If the population has several strata (e.g. packets from different machine rooms or factories), then the increments should be drawn from all the strata, in proportion to their respective sizes.

4.2.2.3 If the sampler finds that the stock available is not adequate to take the number of increments required, he shall arrange a further visit to complete the sampling. Samples taken within 5 d shall be considered as one laboratory sample.

4.2.2.4 The procedure of sampling is illustrated in Figure A.1.

4.2.3 Constitution of the laboratory sample

The laboratory samples are prepared as in 4.1.2.

4.2.4 Constitution of the test sample

The test samples are prepared as in 4.1.3.

5 Sampling mode: over a period of time

5.1 General

The procedures described in Clause 4 are concerned with sampling "at one point in time" [see a) in Clause 1].

For some purposes a sample representing cigarettes available over a period of time (e.g. six months or a year) is required and may be obtained by dividing the sample required into a number of sub-period samples that are obtained and tested at different times. It is important that each sub-period sample be tested at the time of collection and not saved in order to test the whole sample at the end of the period. This avoids potential problems connected with ageing of the sample and ensures that variations over time in both the cigarettes and the laboratory determinations are taken into account in the measure of sample variability. There may be occasions when it is necessary to sample at a point of sale over a period of time. Since the reasons are difficult to define, this procedure is not specified in this International Standard.

5.2 Procedure for sampling over a period of time at the factory

The time period shall be divided into at least five equal sub-periods. In each sub-period, each sub-period sample shall be taken from every sub-period from every factory where the cigarettes are made or imported and distributed. Whenever possible, the number of sub-periods multiplied by the number of sampling points should equal the number of increments required in the laboratory sample. The total number shall be the same as that required for a sample at one point in time and they shall be equally divided between sub-periods.

At each factory, no more than one increment shall be drawn from a sampling point. Sampling points shall be selected from all the possible sample points in the factory.

Principles, sampling and constitution shall be as described in 4.2.

The procedure of sampling is illustrated in Figure A.1.

6 Statistical evaluation and reporting

6.1 Statistical evaluation

There are, potentially, many applications that require sampling of cigarettes manufactured for sale, ranging from the determination of smoke constituent yields to measuring physical properties on the unsmoked product. There are also different purposes for testing such samples. For example, for quality monitoring or to provide statistics for checking that cigarettes comply with on-packet declarations, currently of NFDPM, nicotine and CO.

Despite this diversity of application and purpose, the principles of statistical evaluation are similar for most situations. Laboratory measurements made on the product samples are used to estimate a statistic (e.g. a mean value or difference), which then requires qualification in terms of its statistical variation, usually in the form of a confidence interval.

Although this International Standard is primarily concerned with product sampling, it is also necessary, when formulating an appropriate confidence interval, to incorporate components of statistical variation associated with the product measurement. This is reflected in the confidence intervals given in 6.3 for the purpose of checking that cigarettes comply with on-packet declarations of NFDPM, nicotine and CO.

6.2 Outliers

In any body of experimental data there might be outliers, observations in which something may have gone wrong to give a faulty result. The tests for outliers described in ISO 5725-2 shall be used and its recommended criteria for rejecting observations followed.

6.3 Confidence interval

There are two major sources of statistical variation – the laboratory measurement (analytical) and the product itself. Both the product and the measurements made on it fluctuate over time (both in the short and longer term, see Annex B), whilst analytical measurements also vary between laboratories, even for matched samples of cigarettes. Rounding of reported values provides an additional source of variability that needs to be taken into consideration.

The method described in ISO 2602 to calculate confidence intervals shall not be used because samples taken in accordance with this International Standard are not strictly random.

NOTE The objective of the confidence interval is to ensure that on average only one in every 20 determinations are likely to be outside of this interval purely by chance.

6.4 Applications to the verification of cigarettes yields

In the context of packet labelling, smoke constituent yields (currently NFDPM, nicotine and CO) are determined from laboratory tests carried out by the manufacturer on cigarettes sampled from production. Checks by a designated laboratory would occur later, after the manufacturer has determined and printed its values on the cigarette packet. It follows, therefore, that the statistic, Z, for which a confidence interval is to be obtained can be defined as:

$$Z = M_{\mathrm{m}} - M_{\mathrm{dl}}$$

where

M_{m} is the manufacturer mean;

M_{dl} is the designated laboratory mean obtained at a later date.

The statistical task is then to combine the relevant components of variance in such a way that a confidence interval describes the extent of the variability in the difference, Z, between the mean values obtained by two separate laboratories on different samples of cigarettes. This has been studied in some depth and ISO/TR 22305 [8] sets out the basis for the confidence intervals, Z, given in Table 3 for NFDPM, nicotine and CO. The conclusions within the report are based on practical experience of verifying these measurements in a number of different marketplaces underpinned by a theoretical consideration of the sources of statistical variation. The intervals, Z, given in Table 3 are expressed as percentages of the on-packet declared values.

When samples are obtained at one point in time (i.e. as under 4.1 and 4.2), wider confidence intervals are required since certain longer term components of variance are not 'averaged out' to the same extent.

Table 3 — Confidence interval

Smoke constituent and ISO measurement method	**Sampling**	
	Over a period of time (Clause 5)	**At one point in time** (4.1 and 4.2)
NFDPM (ISO 4387 and ISO 10362-1)	± 15 %	± 20 %
Nicotine (ISO 10315)	± 15 %	± 20 %
Carbon monoxide (ISO 8454)	± 20 %	± 25 %
NOTE These confidence intervals will not be smaller than ± 1 mg for NFDPM, ± 1,5 mg for CO and ± 0,1 mg for nicotine.		

NOTE Although practical experience of confidence intervals at the time of the current revision encompasses only the smoke analytes NFDPM, nicotine and CO, confidence intervals for additional smoke constituents may be added to Table 3 derived in accordance with the principles set out in this standard as experience develops.

7 Sampling report

The sampling report shall include the following particulars:

a) dates between which sampling was carried out;

b) area from which samples were drawn (or the area served by the factories/warehouses sampled);

c) number of times sampling was carried out and the number of increments sampled;

d) number of places sampled, principles of factory/warehouse sampling (detailed tables of number of increments from each factory/warehouse are not necessary);

e) intentional changes to the product, e.g. change in printed smoke yield values;

f) reference to this International Standard, i.e. ISO 8243:2006.

Annex A
(informative)

Flow chart illustration of the sampling in Clauses 4 and 5

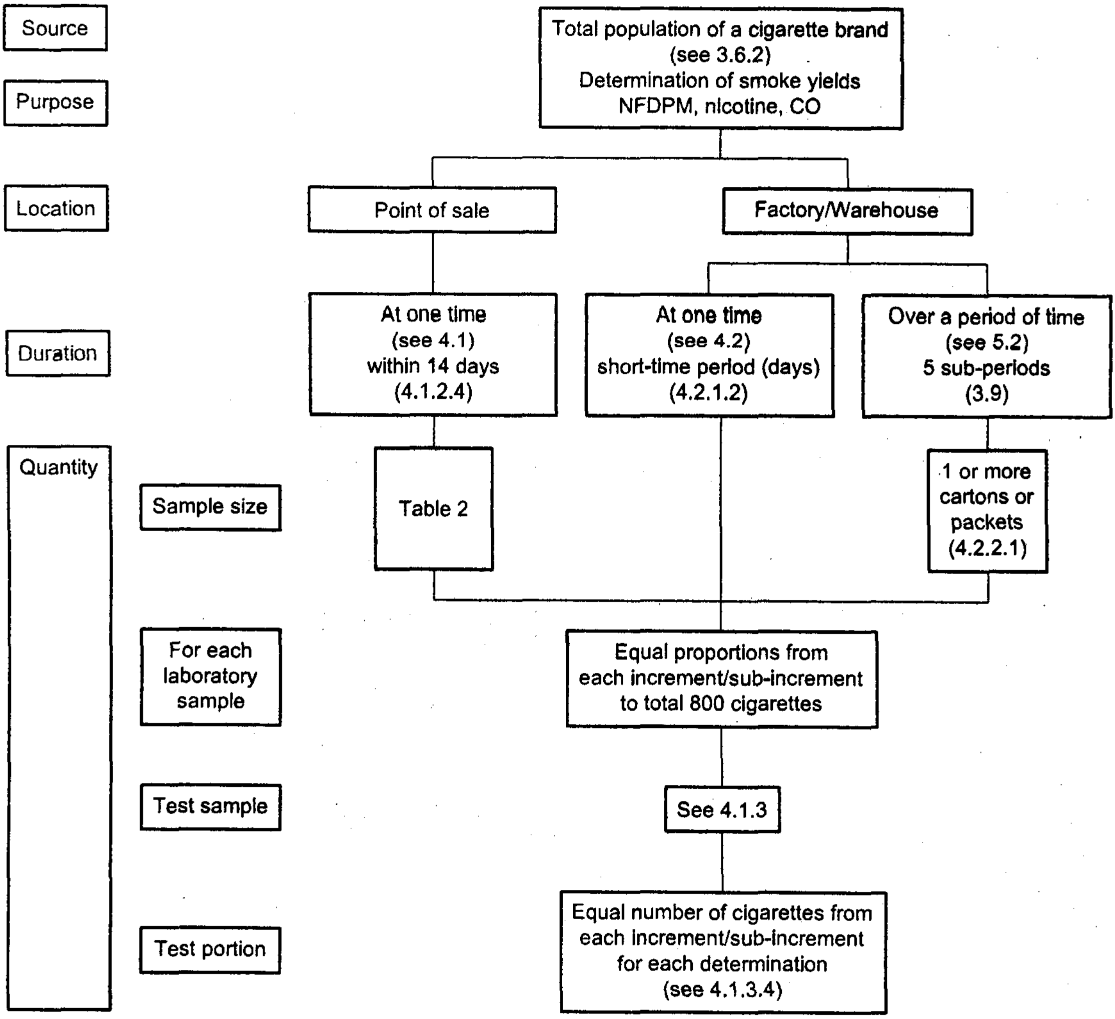
Source
Purpose
Location
Duration
Quantity
Sample size
For each laboratory sample
Test sample
Test portion
Total population of a cigarette brand (see 3.6.2) Determination of smoke yields NFDPM, nicotine, CO
Point of sale
Factory/Warehouse
At one time (see 4.1) within 14 days (4.1.2.4)
At one time (see 4.2) short-time period (days) (4.2.1.2)
Over a period of time (see 5.2) 5 sub-periods (3.9)
Table 2
1 or more cartons or packets (4.2.2.1)
Equal proportions from each increment/sub-increment to total 800 cigarettes
See 4.1.3
Equal number of cigarettes from each increment/sub-increment for each determination (see 4.1.3.4)

Figure A.1 — Flowchart for cigarette sampling

Annex B
(informative)

Sources of variability concerning the choice of sampling procedures

B.1 General

Variability arises from the methods used to test cigarettes (for example, see ISO/TR 22305), but there are also appreciable contributions to the variability of the product as cigarette manufacture continues over a period of time. These are reflected in sources of variability described in B.2 to B.4.

B.2 Short-term variability

It is impossible to precisely control the mass of every cigarette. The moisture content of the tobacco varies around its target value. Paper porosity contains similar variability. Tipping materials are also variable. Thus, the design characteristics of the cigarettes being manufactured at any one time vary in a random fashion around their target values, and these variations give rise to corresponding variations in smoke yields.

B.3 Medium-term variability

Superimposed on the sources of short-term variability are the sources of medium-term variability such as batch-to-batch changes in materials (paper, tipping, filter papers, filter tows), grade substitutions in the blend and wear of machinery.

B.4 Long-term variability

In the long term there are changes in the blend due to different crop years. Machinery replacement programmes and the upgrading of manufacturing processes can influence the product. Suppliers of non-tobacco materials (papers, tipping, etc.) may change. All these sources of long-term variability are added to both the short- and medium-term contributions.

B.5 Conclusion

These terms are described for practical convenience, but it should be remembered that these sources of variability operate as a continuum over time. Experience over numerous years has shown that when attempting to estimate a "true" overall mean (i.e. over all production runs), the contribution to the variability of medium-term effects is larger than that of short-term effects, with the influence of long-term effects being larger than either of these.

The implications of variability on confidence limits are discussed in Clause 6.

Bibliography

[1] ISO 3308:2000, *Routine analytical cigarette-smoking machine — Definitions and standard conditions*

[2] ISO 3402:1999, *Tobacco and tobacco products — Atmosphere for conditioning and testing*

[3] ISO 3534-1:—[1], *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

[4] ISO 3534-2:—[2], *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

[5] ISO 3534-3:1999, *Statistics — Vocabulary and symbols — Part 3: Design of experiments*

[6] ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

[7] ISO 10362-2:1994, *Cigarettes — Determination of water in smoke condensates — Part 2: Karl Fischer method*

[8] ISO/TR 22305, *Cigarettes — Measurement of nicotine-free dry particulate matter, nicotine, water and carbon monoxide in cigarette smoke — Analysis of data from collaborative studies reporting relationships between repeatability, reproducibility and tolerances*

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1) To be published. (Revision of ISO 3534-1:1993)

2) To be published. (Revision of ISO 3534-2:1993)

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This Indian Standard has been developed from Doc: No. FAD 4 (1700).

Amendments Issued Since Publication

Amendment No.	Date of Issue	Text Affected

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